K002233

OCT 1 3 2000

Bio-Vascular, Inc.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: Bio-Vascular, Inc.
2575 University Avenue, Suite 180
St. Paul, MN 55114-1024
Phone: (651) 603-3700
Fax: (651) 642-9018

Contact: Daisy P. Sin, MT (ASCP), CHT (ABHI)
Regulatory Affairs Specialist
Phone: (651) 603-5203
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Alternate Contact: Mary Frick, Director of RA / CA / QA
Phone: (651) 603-3803
e-mail: m.frick@biovascular.com

Date Prepared: July 21, 2000

Common or Usual Name: Surgical mesh

Device Classification Name: Surgical mesh (per 21 CFR section 878.3300)

Substantial Equivalence: Cook Urological's Stratasis Urethral Sling

Device Description:
The Bio-Vascular (BVI) sling is an implantable surgical patch comprised of non-crosslinked bovine pericardium. The BVI sling undergoes proprietary processing that allows neo-collagen formation and neo-vascularization of the implanted device and permits replacement of the device with host tissue, or remodeling.

Statement of Intended Use:
The Bio-Vascular sling is a prosthesis for urinary incontinence treatment, reconstruction of the pelvic floor and repair of rectal or vaginal prolapse.

Summary/Comparison of Technological Characteristics:
The Bio-Vascular sling and the predicate device are substantially equivalent with regards to product configuration, classification code, and packaging. Physical testing of the devices indicate that suture retention, tensile strength, and thickness are substantially equivalent and the materials perform in an equivalent manner. The BVI sling is substantially equivalent to the predicate device with regard to safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2000

Ms. Daisy P. Sin, MT (ASCP), CHT (ABHI)
Regulatory Affairs Specialist
Bio-Vascular, Inc.
2575 University Avenue, Suite 180
St. Paul, Minnesota 55114

Re: K002233
Trade Name: Bio-Vascular Sling
Regulatory Class: II
Product Code: FTM
Dated: July 21, 2000
Received: July 24, 2000

Dear Ms. Sin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R P Ogden

Celia M. Witten, Ph.D., M.D. for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002233

Device Name: Bio-Vascular sling

Indications for Use:

The Bio-Vascular sling is for use as a prosthesis for urinary incontinence treatment, reconstruction of the pelvic floor, and repair of rectal or vaginal prolapse.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MRW for CMW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002233

Prescription Use X
Per 21 CFR 801.109

OR

Over-The-Counter Use______